

Landau teaches a durable hypodermic jet injector apparatus and method. With reference to Figs. 1-4, Landau teaches an aft body section 22 that receives a pressurized gas cartridge 24 (paragraph [0028]). Paragraphs [0030] and [0031] describe use of the device. A pressurized gas cartridge 24 is disposed angularly relative to the device into a recess 32 at the aft end of the aft body section 22 with pivoting door 34 open. The pressurized gas cartridge 24 is inserted as seen in Figs. 2 and 3 with a penetrable end disposed toward a penetrator member 38. Landau then states "[t]he door 34 is then forcefully pivoted closed, to the position seen in Figs. 1 and 4, which results in the pressurized gas cartridge 24 being pivoted into axial alignment with the body 18, and then being forced slightly forwardly within the recess 32, and consequently results in the gas cartridge 24 being impaled upon the penetrator member 38, as seen in Fig. 4. Penetration of the pressurized gas cartridge 24 by the penetrator member 38 (which is a tubular member) communicates pressurized gas through the penetrator member 38, and into the blind bore 40 of a stem member 42 (upon which the trigger sleeve 20 is movably and sealingly carried), and to a valve chamber (to be further explained) through which communication of pressurized gas is controlled by the relative position of the trigger sleeve 20."

The combination of the door 34 and the penetrator member 38 enables the liberation of gas from the pressurized gas cartridge 24 in a manner that may correspond to the function of the initiation device recited in the pending claims.

In this regard, however, the circuit elements of the Landau device comprise the cylinder bore, the cartridge 24, as well as the combination door 34 and penetrator member 38. When the circuit of elements is in an assembled state, the door is necessarily in a closed position as shown in Fig. 1 and thus covers the cartridge 24 as well as the recess 32. In such an instance, the cartridge has to be removed from the recess 32 of the Landau device, within the circuit of elements by at least disassembling that circuit, i.e., by opening the door 34.

Claim 1 recites, among other features, wherein the housing, the circuit of elements being in an assembled state, is accessible from the outside so that the pyrotechnic charge can be inserted into the housing directly in the circuit of elements, independently of the other elements. At least for the reason that any corresponding circuit of elements shown in the Landau device must necessarily be modified in order to allow removal of the pressurized gas cartridge, which the Office Action correctly asserts is not a pyrotechnic charge (cartridge), the pressurized gas charge 24 cannot be inserted into the housing directly in the circuit of elements, independently of the other elements.

For at least this reason, Landau neither teaches, nor would it have suggested, the specific combination of all of the features positively recited in claim 1 upon which the Office Action relies on this reference as teaching.

In response to Applicants previously having made the above arguments, this Office Action in the response to arguments section asserts that these arguments are not considered persuasive. The Office Action improperly characterizes Applicants' arguments and then makes an inappropriate attempt at analogy to support the conclusions of the Office Action. It must be noted that in Landau, in, for example, Fig. 3, the cartridge comprising the pressurized gas is inserted in the recess 32. The pivoting door 34 is pivoted between a pair of rearwardly projecting extensions 36a and 36b (see, for example, paragraph [0030]) in order to impale the gas cartridge 24 on the penetrator 38. This cannot reasonably be considered to teach that the pressurized gas cartridge, which is not a pyrotechnic charge, can be inserted into the housing directly into the circuit of elements independently of the other elements, i.e., the door.

The Office Action concedes that Landau does not teach the use of a pyrotechnic charge. Rather, the Office Action relies upon Castellano or Schwebel as allegedly teaching such a feature, concluding that one of ordinary skill in the art would have predictably replaced the pressurized gas cartridge of Landau with the pyrotechnic charge of either Schwebel or

Castellano in the manner suggested. The analysis of the Office Action in this regard fails for at least the following reasons.

Each of Castellano and Schwebel describe a circuit of elements in which in an assembled state, the initiation device, respectively, the actuating member 20 and the plunger 36, cover the pyrotechnic charge as well as its housing, respectively, the chamber 18 containing the gas, and the housing containing the pyrotechnic charge 25. The result of these varied constructions is that even if one of ordinary skill in the art would have replaced the initiation device (door 34 and penetrator member 38), as well as the pressurized gas cartridge 24, disclosed in Landau with an initiation device and a pyrotechnic charge of either Castellano or Schwebel, the initiation device would still cover the pyrotechnic charge when the circuit of elements is assembled. The housing would still not be accessible from outside when the circuit of elements is in an assembled state. As such, even these asserted combinations of references would not have suggested the combination of all the features positively recited in independent claim 1.

In response to Applicants having made the above argument, the Office Action addresses the Schwebel reference by specifically pointing out that Schwebel shows an initiation device is a small plunger (36) which is depressed and then triggers pyrotechnic reaction through the primer in the cartridges found in elements 25 and 26. The Office Action, as did the previous Office Action, in the Response to Arguments section concludes that one would recognize that the cartridge is separate from the other parts of the house and since Landau teaches that only the cartridge is removable, one of ordinary skill "would recognize that the initiation device of Landau and the gas cartridge could be replaced by the initiation device and pyrotechnic charge of Schwebel where the initiator pivots open to expose an opening for the cartridge." Starting with Castellano, that document teaches that pyrotechnic charges may be substituted for gas powered injectors, but such a teaching cannot be broadly

enough construed to indicate that, in all cases, such a replacement could be made. For example, with the opening door of Landau, it is not reasonable to assert that one may have placed a pyrotechnic charge in that device and initiated the explosive nature of that pyrotechnic charge by closing the door in the manner asserted by the Office Action without a) exposing the user to a dangerous condition and therefore b) rendering the primary (Landau) device unsuitable to its intended purpose. In other words, Castellano must be reasonably limited in its discussion of how the cartridge of compressed gas may be replaced by a pyrotechnic device, *i.e.*, in the same specific location at the end of the Castellano device.

Applicants' disclosure discusses the inherent shortfall, and potentially dangerous nature, of certain of the prior art devices at least at page 2, lines 26-29 where it is discussed that "in a device of this kind (discussing the prior art), it may prove dangerous to fix the reserve of gas on the one end of this device, since said reserve of gas is then easily accessible to the user and may well be damaged." The location of the cartridge as disclosed in Castellano's device leads to such a high risk of actuating the pyrotechnic charges of the penetrator at the wrong time. One of the goals of the subject matter of the pending claims is precisely to avoid any manipulation resulting in initiating the pyrotechnic device at the wrong time (see, *e.g.*, page 10, line 36 - page 11, line 2). For at least this reason, one of ordinary skill in the art attempting to avoid any damage to the reserve of gas would understand that in Schwebel the pyrotechnic charge is not mounted at the end of the injection device, but is rather fixed under a firing pin mounted on a plunger (see, *e.g.*, col. 3, lines 12-26). It remains unclear even given the strained approach that the Office Action takes to combining these references, how it can be adequately shown that one of ordinary skill in the art would have predictably combined these teachings in the manner suggested by the Office Action with any reasonable expectation of success. The Office Action alleges that it would have been obvious to replace the cartridges of Landau with the pyrotechnic charge of Schwebel since it is well

known in the art, as taught by Castellano, that gas powered injectors and pyrotechnic injectors are functional equivalents and may be predictably substituted for one another.

Such a conclusion overlooks significant design modifications that would have had to have been undertaken with the Landau device in order to accommodate a pyrotechnic charge of Schwebel without hazarding the operator, thereby, on its face, making the alleged combination impermissible. MPEP §2142 instructs that the proper standard by which to determine obviousness requires (1) that the Examiner step backward in time into the shoes of the hypothetical "person of ordinary skill in the art," (2) that "[i]n view of all the factual information the Examiner must then make a determination whether the claimed invention 'as a whole' would have been obvious at the time to that person," and (3) that any knowledge gained from Applicants disclosure must be put aside at reaching this determination in order to avoid the tendency to resort to the impermissible application of hindsight reasoning based on the roadmap provided by Applicants' disclosure. This standard is completely overlooked here where it is simply and plainly asserted that the alleged substitution would have been clear to one of ordinary skill in the art at the time this application was filed. Even post-KSR, the analysis supporting an obviousness rejection must be explicit and must be reasonable, supported by objective evidence of record. The Supreme Court in *KSR* approved the conclusions set forth in the decision of the Federal Circuit in *In re Kahn* (citations omitted) that "rejections on obviousness grounds cannot be sustained with mere conclusory statements. Instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." This standard is not met here with the mere conclusory statement that one of ordinary skill in the art would have replaced a gas generator in a device in which a door is closed to impale that gas cartridge on a pin with some pyrotechnic device by which one would have closed the door to initiate the explosion. In other words, there is simply no rational underpinning for the alleged articulated reasoning.

Bellhouse does not mention the use of a pyrotechnic cartridge as a gas generator. Further, Bellhouse teaches that a replaceable compressed gas cartridge 22 with a reservoir 24 containing the active particle is placed in housing 20 covering the cartridge 22 before being inserted into the housing 56 of the body 4. In this regard, Bellhouse does not make up for the identified shortfall in the application of the other applied references to the subject matter of the pending claims.

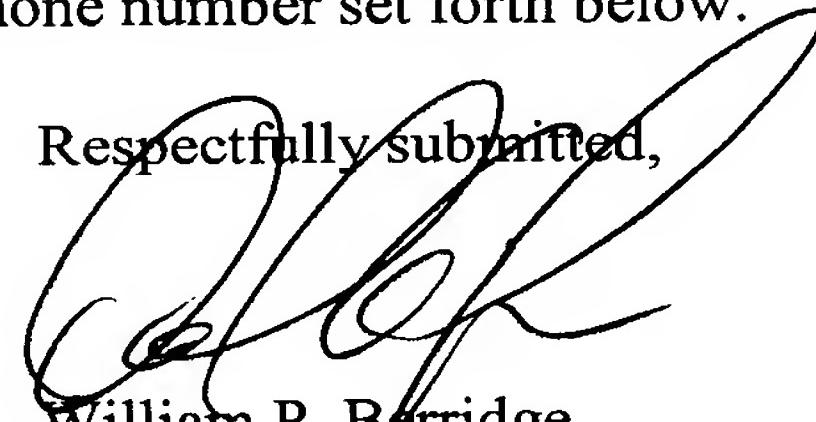
For at least the foregoing reasons, no permissible combination of Landau with Castellano, Schwebel or Bellhouse can reasonably be considered to have suggested the combination of all of the features positively recited in independent claim 1. Further, claims 2-12 also would not have been suggested by any combination of these references for at least the respective dependence of these claims directly or indirectly on an allowable base claim, as well as for the separately patentable subject matter that each of these claims recites.

Accordingly, reconsideration and withdrawal of the rejections of claims 1-12 under 35 U.S.C. §103(a) as being unpatentable over the varying combinations of applied references enumerated in the Office Action are respectfully requested.

In view of the foregoing, Applicants respectfully submit that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-12 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number set forth below.

Respectfully submitted,



William P. Berridge
Registration No. 30,024

Daniel A. Tanner, III
Registration No. 54,734

JAO:DAT/cfr

Date: October 14, 2008

OLIFF & BERRIDGE, PLC
P.O. Box 320850
Alexandria, Virginia 22320-4850
Telephone: (703) 836-6400

DEPOSIT ACCOUNT USE AUTHORIZATION Please grant any extension necessary for entry; Charge any fee due to our Deposit Account No. 15-0461
--